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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,128	04/12/2007	Masakazu Katsumata	46884-5485	3225
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HINES, JANA A				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/583,128

**Applicant(s)**

KATSUMATA ET AL.

**Examiner**

JaNa Hines

**Art Unit**

1645

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 5-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-4 and 18-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date 6/16/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group II in the reply filed on June 5, 2009 is acknowledged. Therefore claims 1 and 5-15 are withdrawn from consideration. Claims 2-4 and 18-25 are under consideration in this office action.

***Priority***

2. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the

prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference

in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on June 16, 2006 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 18-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for:

a) The toxic substance assay method according to wherein in the second step, a standard sample to be compared with is used as the comparison sample, the photosynthetic sample is mixed with the standard sample to prepare a standard measurement solution that is the comparison measurement solution, the standard measurement solution is left to stand for the predetermined standing time, and then after illuminating light onto the standard measurement solution for the predetermined

illumination time, the light amount of the delayed fluorescence that is emitted is measured to acquire the comparison measurement result.

b) The toxic substance assay method, wherein in the second step, another aqueous solution sample is used as the comparison sample and a measurement result, acquired on another test measurement solution that is the comparison measurement solution prepared by mixing the other aqueous solution sample with the photosynthetic sample, is prepared as the comparison measurement result.

c) The toxic substance assay method, wherein, in the second step, a measurement result, acquired in advance for the comparison measurement solution, is prepared as the comparison measurement result.

d) The toxic substance assay method, wherein in the first step and the second step, the test measurement solution and the comparison measurement solution are left to stand for a predetermined standing time with light conditions being varied in each measurement, and in the third step, a variation of the comparison values according to the light conditions is evaluated.

e) The toxic substance assay method, wherein the densities of the photosynthetic sample in the test measurement solution and in the comparison measurement solution are within a range of densities that are in a proportional relationship with the light amount of delayed fluorescence.

f) The toxic substance assay method, wherein in the first step and the second step, the test measurement solution and the comparison measurement solution are homogenized before measuring the light amount of delayed fluorescence.

Applicant did not point to support in the specification for the toxic substance assay method as claimed. Moreover, applicant failed to specifically point to the identity or provide characteristics of a toxic substance assay method. Thus, there appears to be no teaching of the toxic substance assay method as instantly claimed. Therefore it appears that the entire specification appears to fail to recite support for the newly toxic substance assay method. Thus, applicants must specifically point to page and line number support for the toxic substance assay method as recited by the amendment. Therefore, the claims incorporate new matter and are accordingly rejected.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2-4 and 18-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of the claims is drawn to assaying a toxic substance present in an aqueous solution sample to be tested, the toxic substance assay method. There is no correlation step which correlates assaying a toxic substance present in an aqueous solution sample to be tested with the assay values are temporal variations of the light amounts of delayed fluorescence acquired in the first step and the second step, and the comparison value is a value obtained by determining a difference of the temporal variations. Therefore, the goal of the preamble is not commensurate with the steps of the method that are drawn to a toxic substance assay method.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 2-4 and 18-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt et al., (Biochimica et Biophysica Acta. 1987. Vol. 891:22-27).

The claims are drawn to a toxic substance assay method of assaying a toxic substance present in an aqueous solution sample to be tested, the toxic substance assay method comprising: a first step of mixing a photosynthetic sample, having a photosynthetic function, with the aqueous solution sample to prepare a test measurement solution, letting the test measurement solution stand for a predetermined standing time, and then after illuminating light onto the test measurement solution for a predetermined illumination time, measuring a light amount of a delayed fluorescence that is emitted; a second step of letting a comparison measurement solution, prepared by mixing the photosynthetic sample with a comparison sample, stand for the predetermined standing time, and then after illuminating light onto the comparison measurement solution for the predetermined illumination time, measuring a light amount of the delayed fluorescence that is emitted to thereby prepare a comparison measurement result; and a third step of computing assay values based on the light amounts of delayed fluorescence, respectively acquired in the first step and the second step, and determining a comparison value of the assay values to assay the toxic substance present in the aqueous solution sample, wherein the assay values are temporal variations of the light amounts of delayed fluorescence acquired in the first step and the second step, and the comparison value is a value obtained by determining a difference of the temporal variations.



Schmidt et al., teach long-term delayed luminescence in blue-green algae, *Scenedesmus obliquus* and the influence of exogenous factors. Schmidt et al., teach long-term delayed luminescence for a predetermined time, varying from 0.3s up to several minutes has been studied in wild type and several pigment mutants of *Scenedesmus obliquus* during the life cycle and under the influence of various exogenous parameters such as herbicides, different pH values, temperature, preillumination and the diurnal rhythm of synchronized cells (abstract). Schmidt et al., teach the investigation of spectral and kinetic properties where complex decay kinetics as well as the comparison of excitation and emission spectra of long-term delayed luminescence with those of prompt systems associated both with PSI and PSII in long-term delayed luminescence (page 22, col.1). Schmidt et al., teach particularly a long term intermediate showing maximal luminescence after excitation with a far red light pulse was attributed to pigments of PS I (page 22, col. 1-2). Schmidt et al., teach prior to illumination, cell suspensions were treated with inhibitors (page 22-23, col. 2-1). Device and conditions for measuring long term delayed luminescence have been described previously described and were modified for measuring algae suspensions (page 23, col. 1). Figure 1 shows the kinetics of long-term delayed luminescence (LTDL) as a function of the development stage. Schmidt et al., teach preirradiating light as exemplified by Figure 2D, the LTDL intermediate is strongly enhanced by irradiation with light (page 23, col. 2). Schmidt et al., teach the observation is consistent with the dependence of prompt fluorescence on the wavelength of preirradiation (page 23, col.2). Schmidt et al., teach Analysis of LTDL by treatment with various inhibitors applied

immediately before the 1 s light induction or by other treatments (page 24, col. 1).

Figure 2 shows both the test measurement solution and comparison measurement solution and computing assay values based on the light amount of delayed fluorescence acquired by each and determining a comparison value. Figure 2A shows dark incubation, while Figure 2F shows examples for the dependency of the kinetics of LTDL on temperature. Schmidt et al., teach the induction potency for LTDL (initial rate of quantum emission) in the mutant algae by blue light, see Figure 3. Schmidt et al., teach kinetics of LTDL as a function of pH of the exogenous medium.

Therefore Schmidt et al., teach the invention as claimed.

### ***Conclusion***

6. No claims allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/  
Examiner, Art Unit 1645

/Mark Navarro/  
Primary Examiner, Art Unit 1645